UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Hon. Patti B. Saris
United States of America, ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., CIVIL ACTION NO. 06–CV-11337-PBS	)	

UNITED STATES' MEMORANDUM OF LAW IN SUPPORT OF CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT AND IN OPPOSITION TO ABBOTT LABORATORIES INC.'S PARTIAL MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

The United States respectfully submits this brief in support of its motion for partial summary judgment and in opposition to Abbott Laboratories Inc.'s (Abbott) motion for partial summary judgment. In its motion for summary judgment, Abbott states that this is a unique case. In fact, Abbott's conduct comports with that of other pharmaceutical companies previously found liable for their drug pricing fraud. There is little factual disagreement about the fraud the United States alleges against Abbott, much of which is apparent from irrefutable data. For example, there is no dispute that Abbott reported list prices for its products that were unmoored to its actual transaction prices and that those prices were many times the actual sales prices for the four Abbott drugs at issue in this case. The record also reveals that Abbott employees acknowledged that these list prices were used by publishers to calculate AWPs and by state and federal government agencies to set payment levels for Abbott's drugs. (US-A-SF ¶¶ 29-38)

To borrow Abbott's characterization, though, there are two unique elements to this case that sets it apart from the cases against its co-defendants. First, unlike Roxane and Dey, Abbott operated a home infusion business that directly shared in the spreads for its drugs. (US-A-SF ¶¶ 132-147) Second, Abbott tacitly acknowledged the fraudulent nature of its price reporting conduct in April 2001 by reducing its reported prices for the drugs at issue, in part in response to investigations by the United States Department of Justice and Congressional investigators. (US-A-SF ¶¶ 56-58, 60-64) The simple fact is if Abbott had reported its prices in 1991-2001 as it began to in April 2001, this suit would never have been brought. The fraud began and ended with Abbott's conduct. Consequently, the United States is moving for partial summary judgment on certain elements of its False Claims Act (FCA) claims on the Medicaid claims alleged in the

Amended Complaint, namely on the elements of falsity, materiality, causation, and scienter. In addition, the United States is moving for partial summary judgment on several of Abbott's affirmative defenses.

The United States also opposes Abbott's motion for partial summary judgment in its entirety. The substance of Abbott's summary judgment motion is focused almost exclusively on damages and statute of limitations issues premised on flawed and disputed facts and arguments.[1] Most of the arguments Abbott advances are addressed in the United States' Common Memorandum of Law in Support of Cross-Motions for Partial Summary Judgment and in Opposition to the Defendants' Motions for Summary Judgment (U.S. Common Brief), filed contemporaneously.[2] Three unique issues on which Abbott moves for summary judgment are addressed herein: (1) the Government's inclusion of additional allegations in the Amended Complaint about Abbott's Home Infusion business; (2) the use of average wholesale prices (AWPs) as a proxy for unpublished wholesale acquisition costs (WAC); and (3) arguments regarding claims sampling.

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[1]There is reference in Abbott's brief to an alleged intentional government policy to overpay for drugs for Abbott's customers. *See* Abbott's Memorandum in Support of its Motion for Partial Summary Judgment (Abbott brief) at 1-4, 22-25, filed June 26, 2009 (Dkt. No. 6186). There is no evidence of any such government policy. Rather, Abbott raises a meritless argument that is a pure creation of litigation. The extent to which evidence can be presented to make this policy argument will be addressed by the United States in a motion *in limine*. Abbott admitted in discovery that Medicare or Medicaid reimbursement or cross-subsidization of dispensing fees and providers' costs never influenced or impacted Abbott's pricing conduct. (US-A-SF ¶ 40)

[2]Almost all of Abbott's damages-related arguments are addressed in § IV(A) of the Common Brief. Only the "AWP-Proxy" argument is separately addressed in this brief. *See* § III(F)(1) *infra*. Abbott's Due Process and estoppel/failure to mitigate damages § IV(A)(3), (C), and D of the Common Brief. Abbott's Unjust Enrichment arguments are addressed in § IV (B). Abbott's unique Home Infusion/relation back arguments are addressed in this brief. *See* § III (F)(2), *infra*.

II. SUMMARY OF UNDISPUTED FACTS

A. Overview of Abbott, Abbott Products and Abbott Spreads

Abbott manufactures and sells drugs, medical products and devices. From 1991 until after 2001, Abbott operated a division it called the Hospital Products Division (Abbott HPD), which sold the drug products that are at issue in this lawsuit: Vancomycin; Dextrose; Saline; and Sterile Water (Subject Drugs). (US-A-SF ¶¶ 2-4) HPD was divided into two components: the Hospital Business Section (HPD HBS) and Alternate Site (HPD Alt Site). (US-A-SF ¶ 9) The United States' claims principally involve sales to HPD Alt Site customers.

Abbott's HPD Alt Site consisted of two business units, Alternate Site Product Sales (ASPS) and Alternate Site Home Infusion (Home Infusion). (US-A-SF ¶ 10) ASPS sold to the non-hospital market through contracts and group purchasing organization (GPO) arrangements. (US-A-SF ¶ 10) Home Infusion entered into partnership agreements with outpatient facilities, whereby it provided consigned cost-free inventory and billing, collection and other services. (US-A-SF ¶ 10) Home Infusion entered into "revenue share" arrangements with revenue-share customers ("Home Infusion partners"). Home Infusion also performed third-party billing and collections for Abbott's wholly owned pharmacies, in addition to providing other services. (US-A-SF ¶¶ 10-11) For example, Home Infusion assisted its partners with submitting reimbursement claims for Medicaid and Medicare. (US-A-SF ¶ 134)

The Subject Drugs are four multisource generic products sold under 44 different national drug codes (NDCs) that differentiate packaging and volumes of these products. (US-A-SF ¶¶ 1-3). One of the four drugs at issue is Vancomycin, a potent antibiotic. (US-A-SF ¶¶ 5) The other Subject Drugs, Dextrose, Saline and Sterile Water, are generic fluid products used for irrigation,

hydration and the mixing of other drugs.[3] (US-A-SF ¶ 8) During the claims period, Abbott was subject to a Rebate Agreement with Health Care Financing Administration (HCFA);[4] its products, including the Subject Drugs, are eligible for reimbursement under Medicare and Medicaid. (US-A-SF ¶¶ 4, 12).

B. Abbott's Price Reporting Practices

1. List Prices

The AWPs at issue were inflated because Abbott reported inflated list prices[5] to price reporting compendia or publishers. From 1991 until at least 2001, Abbott HPD defined list price as the catalogue price for non-contract customers buying directly from Abbott. (US-A-SF ¶¶ 29, 51) Abbott now concedes there were large spreads (of up to 1685 percent) between the list price and contract prices. (US-A-SF ¶¶ 48, 57) Abbott admits that its list prices increased three to five percent each year from 1991 to 2001, while at the same time the contract prices on the Subject Drugs remained generally constant or even decreased in some cases due to competitive forces. (US-A-SF ¶¶ 42, 44). In short, the prices Abbott reported were not the "best estimate of the prices generally and currently paid by providers for a drug." *See* 42 C.F.R. § 447.301. In contrast, another Abbott division, the Pharmaceutical Products Division (PPD), set its list prices,

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[3]Abbott launched these products decades ago. Most are low cost to Abbott (on average approximately $0.20 to $2.00), ubiquitous in the marketplace, and used in high volumes daily in the Alt Site market. (US-A-SF ¶ 8)

[4]HCFA, renamed in 2001 as the Centers for Medicare & Medicaid Services (CMS), is the agency of the Department of Health and Human Services that administers the Medicare and Medicaid programs.

[5]Abbott viewed the terms "Catalog Price", "Direct Price", and "Trade Price" to all refer to the same price, its "list price". These terms were used interchangeably within Abbott HPD.

which were reported to the three publishers identified below for nearly all of its products,[6] using a figure that was only five percent higher than PPD's wholesale acquisition cost (WAC)(net of chargebacks and discounts) on the products. (US-A-SF ¶ 68, 70). The list prices for the drugs at issue in this case are set forth in Appendices to the Declaration of Patrick Ormond (Ormond Decl.) and discussed further below. (US-A-SF ¶¶ 19-21)

2. Reporting to the Publishers

Since 1991, Abbott has regularly reported list prices to three Publishers: First Databank, Red Book, and Medispan (collectively the Publishers). (US-A-SF ¶ 83). The Publishers determined Abbott's AWP by applying an 18.75 percent mark-up to the list price. (US-A-SF ¶ 88) Abbott HPD employees, including Abbott HPD's liaison to the Publishers, were aware of the application of the 18.75 percent mark-up to list price. (US-A-SF ¶¶ 33, 90, 104) Abbott communicated routinely with the Publishers regarding its reported prices. (US-A-SF ¶ 83). Those communications included verifying the accuracy of its prices as published, when requested from at least one Publisher. (US-A-SF ¶ 36) Abbott's Home Infusion contract marketing manager, David Brincks, agreed that, in the context of the Vancomycin price in 1995, he understood there was a formulaic relationship between the list prices set by Abbott and the AWPs that were published for those Abbott products. (US-A-SF ¶ 36) In addition, several Abbott employees understood the relationship between list prices and AWPs reported by the Publishers. (US-A-SF ¶¶ 31, 36, 83). As one employee succinctly described, "AWP is a function of list." (US-A-SF ¶ 33). The AWPs for the drugs at issue in this case are set forth in

[6]The exceptions are the PPD Erythromycin products, which are the subject of Relator's action pending in this MDL. *U.S. ex rel. Ven-A-Care, et al. v. Abbott Laboratories, Inc.*, No. 07-11618-PBS.

Appendices to the Ormond Decl. and discussed further below. (US-A-SF ¶¶ 19-21)

By controlling list price, Abbott controlled the AWP for its drugs. This control is best exemplified by Abbott's reporting in 1995 for the Subject Drug, Vancomycin. Abbott changed the prices it reported for Vancomycin in or around late March 1995. Starting with a high per unit list price of $50.90 on its 1 gram flip-top packaged version of Vancomycin, Abbott dropped that reported price to $15.00. Subsequently, after receiving inquiries, Abbott raised the reported list price on this product at first to $32.95, and then again to $52.94 by May of that same year. A memorandum drafted by a reimbursement manager at HPD Alt Site warned "[h]aving a published list price which is high allows a provider to bill at that list price. Some customers who were buying our Vanco at a deep discount off list may ask about the price change." (US-A-SF ¶ 81) This had a corresponding effect of raising and lowering the AWP on this product from a $60.44 to a low of $17.81, and back up to a high of $62.86, all within less than a two month span. None of these prices reflected the price generally and currently paid by providers. (US-A-SF ¶¶ 71-81)

3. Use of Abbott's Reported Prices

Virtually every state Medicaid program used Abbott's AWPs to set payment levels for Abbott products. *See generally* U.S. Common Brief; (US-C-SF ¶¶ 28-84). The reimbursement methodology employed by every state Medicaid program included a "lower of" component. (US-C-SF ¶¶ 29-30). A very common methodology was that a state set its drug reimbursement at the lower of (1) an Estimated Acquisition Cost (EAC), usually based on a published AWP and sometimes based on a published WAC; (2) the Usual & Customary Charge (U&C); (3) a

Maximum Allowable Cost (MAC); or (4) Federal Upper Limit (FUL).[7] A limited number of states reimbursed based on the lower of (a) EAC plus a dispensing fee; (b) U&C; (c) the FUL (if any) plus a dispensing fee; (d) the SMAC (if any) plus a dispensing fee; or (e), if applicable, the "DOJ Price" plus a dispensing fee.[8] (US-A-SF ¶¶ 17, 22) In turn the states made claims for funding and payment to the Federal Government based on their payments to state providers. *See* U.S. Common Brief.

Because states incorporate AWPs and/or WACs into their determination of EAC, and EAC is one of several price points considered in determining the "lower of" reimbursement amount, there is no genuine issue that inflated AWPs and/or WACs are materially and causally connected to the submission of claims to the government for the Subject Drugs.

Further, Abbott knew that AWP was used to determine drug payments by third-party payors. (US-A-SF ¶¶ 31-38) Abbott employees admitted that providing published AWP information to customers was an essential component to spread marketing. (US-A-SF ¶ 30) Abbott further admitted that it did provide AWP and spread related information to its HPD Alt Site GPO customers, if requested, or if needed as part of the GPO bid process. (US-A-SF ¶ 96) On at least one occasion, Abbott supervisors armed the entire HPD Alt Site sales force with AWP information to use for marketing purposes. (US-A-SF ¶ 103).

4. Department of Justice and Congressional Investigations

Abbott ultimately reduced its reported prices in 2001 in the face of United States

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[7]There were no FULs for any of the Abbott Subject Drugs.

[8]The "DOJ Price" refers to prices provided in 2000 by the United States Department of Justice and the National Association of Medicaid Fraud Control Units ("NAMFCU") and published by FDB. (US-A-SF ¶ 17).

Department of Justice and Congressional investigations. (US-A-SF ¶¶ 56, 58, 66-70) Abbott received its first notice of the United States' investigation on January 22, 1996 – approximately seven months after the relator's *qui tam* was filed in this matter – when the Attorney General issued a Civil Investigative Demand (CID) to Abbott seeking information pertaining to price reporting and AWP spreads for all of the Subject Drugs, except Sterile Water. (US-A-SF ¶ 111). On October 31, 1997 and August 28, 2000, HHS-OIG issued two subpoenas to Abbott requesting documents and information pertaining to its HPD list price reporting and AWP spread maintenance practices, including for the Subject Drugs. (US-A-SF ¶ 111)

On September 30, 1999, the Department of Justice issued a letter notifying Abbott of the relator's *qui tam* suit and the allegations. (US-A-SF ¶ 111). In October and November of 1999, Abbott counsel and counsel for the United States met to discuss this matter.[9] (US-A-SF ¶ 112) (November 3, 1999 Letter from DOJ counsel Reed Stephens to Abbott counsel Dan Reidy, referencing an October 27th meeting).

On October 31, 2000, Abbott's chief executive officer, Miles White, received a letter from Representative Fortney "Pete" Stark which notified Abbott that Congress was investigating its price reporting. In it, Congressman Stark asserted that Abbott "intentionally reported inflated prices and has engaged in other improper business practices" and stated his view that "the price manipulation conduct was in no way required by or consistent with existing reimbursement laws

[9] Subsequent to this discussion, Abbott joined with other potential defendants in the *qui tam* in position papers submitted in 2000 to the Department of Justice arguing against intervention. (US-A-SF ¶ 113) (March 17, 2000 Letter from Defendants to Assistant Attorney General David Ogden; August 25, 2000 follow-up letter to Assistant Attorney General Ogden; September 1, 2000 letter from Dan Reidy to Reed Stephens joining the defendants' position paper; October 5, 2000 follow-up letter from defendants to Assistant Attorney General Ogden.)

or policies." (US-A-SF ¶ 66) He urged Abbott to stop its reporting of inflated prices and asked CEO White to share the letter with Abbott's "Board of Directors and in particular the Board's Corporate Integrity Committee." (US-A-SF ¶ 66)

5. The 2001 Price Reduction

In 2000 and 2001, at the time Abbott received the Stark Letter, Richard Gonzalez served as the vice president and, later, president of Abbott's Health Systems.[10] (US-A-SF ¶ 13) After being notified of the 2000 HHS-OIG subpoena, Mr. Gonzalez requested a review and investigation of the disparities between HPD's list prices and contract prices. (US-A-SF ¶ 56, 65, 67). Abbott subsequently adopted the PPD list price formula of WAC plus five percent and adopted a definition of WAC that took into account "chargeback processing after the end sale to a contract provider." (US-A-SF ¶¶ 56-58, 60, 69-70). This resulted in the lowering of its list price by 70 to 90 percent, bringing Abbott's prices more closely in line with its prevailing contract prices. These price reductions reduced Abbott's spreads that had ranged from 229 percent to 1685 percent down to ranges of 27 percent to 340 percent. (US-A-SF ¶¶ 57-58). By Abbott's own admission, the decision to lower its HPD list prices, including the prices on the Subject Drugs, was the "right thing to do." (US-A-SF ¶ 64)

C. Abbott's Home Infusion Operations

The significance of AWPs and spreads to HPD Alt Site was perhaps no more acute than in its Home Infusion operations. Home Infusion operated its own pharmacies, which billed Medicare and Medicaid for its dispensed products. (US-A-SF ¶ 132) In addition to maintaining

[10]Abbott's Health Systems had oversight over HPD in 2000 until at least 2003. Mr. Gonzalez had previously served as the senior vice president and then president of HPD from 1998 to 2000. (US-A-SF ¶ 13)

its own pharmacies, Home Infusion's predominant business model involved partnering with outpatient facilities to help get them into the home infusion business. (US-A-SF ¶¶ 134-143). In exchange for providing its consigned goods and broad services at no separate charge, Abbott received a percentage of the Home Infusion partners' total collected billings – including any spreads – from payors, including Medicare and Medicaid. (US-A-SF ¶¶ 135-137, 142).[11] Abbott promoted its Home Infusion arrangements as "risk sharing" because if the Home Infusion partner did not collect for a patient, then the partner did not have to pay for the Abbott products and services provided.[12] (US-A-SF ¶ 141)

III. ARGUMENT

The United States is moving for partial summary judgment on elements of its FCA Medicaid claims. In addition, the United States is moving for summary judgment on Abbott's Sixth (release), Eleventh (laches, estoppel and waiver), Twenty-Fifth (a failure to mitigate

[11]Abbott billed and collected Medicare and Medicaid reimbursement based on the AWP spreads on its own products, even though its only out-of-pocket costs were the cost of the product and the services and carrying costs associated with storing and dispensing the product. These are not part of the ingredient cost reimbursement benefit. (US-A-SF ¶ 132)

[12]Abbott consigned its products to its Home Infusion partners, who would bear no inventory carrying costs and performed a broad array of services, from start-up engineering, training, consulting, billing Medicare and Medicaid for the partners, while contemporaneously dunning patients for co-pays and denying insurance claims predicated upon the inflated AWPs. (US-A-SF ¶¶ 134-143) Abbott contracted with its customers to use and recommend its products to clients. If the Home Infusion partner used non-Abbott products for its patients, not only did the partner pay for that non-Abbott product but, by contract, the cost to the Home Infusion partner for the non-Abbott product was not deducted from the percentage share of the gross revenues that it was contractually required to pay Abbott. (US-A-SF ¶ 137) The only way that Abbott's Home Infusion business model made business sense was if there was enough profit over and above ingredient cost for Abbott products that would permit both Abbott and its partners to receive some form of return on investment. The spread collected on Abbott's product invariably afforded that profit cushion. (US-A-SF ¶¶ 146-147)

damages), Thirty-Eighth (government knowledge), and Forty-First (contributory or comparative fault) affirmative defenses. These defenses all are unsupported by the law. *See* Abbott Laboratories Inc.'s Answers and Defenses to the United States' First Amended Complaint at pp. 37-38, 40, 45-46 (Dkt. No. 5188). The arguments on those affirmative defenses are set forth in the U.S. Common Brief.

A. The United States Is Entitled to Partial Summary Judgment Regarding the Falsity of Abbott's Reported Prices for the Drugs in this Case.

As noted in the Common Brief, claims presented to the government are false if they are premised on a fraudulent course of conduct that inflated federal payments for Medicaid drug ingredient costs, violating 31 U.S.C. § 3729(a)(1). U.S. Common Brief § II.A. Further, false price reporting by Abbott constituted false statements material to false or fraudulent claims, violating 31 U.S.C. § 3729(a)(1)(B).[13] Id. Below is a factual discussion and legal analysis showing how Abbott's individual price reporting for the Subject Drugs during the claims period resulted in false statements and false or fraudulent claims to the United States.

1. Abbott Reported Inflated Prices to the Publishers and Controlled the AWP.

As noted in the common brief, federal Medicaid regulations called for a state Medicaid program to pay the estimated acquisition cost of the drug, along with a reasonable dispensing fee.

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[13]The FCA was recently amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (FERA), enacted May 20, 2009. Section 3729(a)(1)(B) was formerly § 3729(a)(2), and is applicable to this case by virtue of § 4(f) of FERA, while § 3729(a)(1) of the statute prior to FERA remains applicable here. "The amendments made by this section shall take effect on the date of enactment of the Act and shall apply to conduct on or after the date of enactment, except that (1) subparagraph (B) of section 3729(a)(1), as added by subsection (a)(1), shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. 3729 et seq.) that are pending on or after that date . . . ." FERA, § 4(f).

42 C.F.R. § 447.301.[14] EAC is defined in the Medicaid regulations as the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers. 42 C.F.R. § 447.301.

Throughout the claims period, Abbott reported inflated prices for the Subject Drugs to all three Publishers. (US-A-SF ¶¶ 14-24) These prices were not remotely related to the estimated acquisition cost for Abbott drugs. Specifically, employees at Abbott's HPD reported what it called list prices to contacts at the Publishers. (US-A-SF ¶¶ 14-24, 93-94). As indicated above, list prices are prices that Abbott published in catalogues that allegedly reflected prices at which Abbott sold its products to non-contract customers. The documents transmitting the relevant list prices to the Publishers between 1991 and 2003 are attached as exhibits to the Lavine Declaration (Lavine Decl.). (US-A-SF ¶¶ 20-24) Abbott admits that these prices had no relationship to the prices actually charged by Abbott to its customers for the drugs at issue. (US-A-SF ¶ 61) As discussed below, the inflated list prices were the basis from which the AWPs were determined by the Publishers and, consequently, were the prices reimbursed by government payors.

Appendices to the Ormond Declaration are a series of charts that aggregate, among other things, all the list prices reported by Abbott to the Publishers during the claims period. (US-A-SF ¶ 23) As is evident from the charts, Abbott increased the list prices for the Subject Drugs every year until 1999. That fact is undisputed by Abbott. (US-A-SF ¶ 42) The list prices increased even though the drugs were generic and the average transaction prices in the

[14]The citations herein are to the federal regulations governing Medicaid drug payments that were in effect prior to October 1, 2007. The claims at issue arose before that date.

attachments show that the competitive marketplace caused the actual prices charged to customers to decrease. *See* Ormond Decl. at Appendices 1-44. (US-A-SF ¶ 56) In April 2001, after becoming aware of the federal investigation and receiving correspondence from Representative Stark, Abbott drastically reduced the reported prices for its drugs. (US-A-SF ¶ 56) At that time, Abbott's reported prices began more closely to approximate the actual amounts charged to customers, although the list prices did still exceed those charges – just not at the same level as prior to April 2001. (US-A-SF ¶ 58) As just one example, the list price for Vancomycin (00074-6533-01) plummeted from $64.35 in 2000 to $14.89 in 2002 – a drop of over 432 percent. (US-A-SF ¶ 56)

Abbott employees understood a correlation between AWP and reimbursement. Certain HPD employees knew that the Publishers used Abbott's list prices to determine AWPs. (US-A-SF ¶¶ 31-38) The Publishers determined Abbott's AWP by adding a mark-up of 18.75 percent to Abbott's reported list price. Abbott even directed Redbook as to what mark-up over list price to use. Abbott employees were aware of the 18.75 percent mark-up. This mark-up was fixed throughout the claims period, until the 2001 price change when FDB changed the mark-up to 25 percent over WAC. (US-A-SF ¶¶ 33, 36, 76, 88-90) On April 3, 2003, Redbook changed to a 20 percent mark-up on list price after consulting with Abbott. Abbott verified the prices reported for its products in the Redbook. (US-A-SF ¶ 92) A further example of Abbott's control over AWP is reflected in Abbott's manipulation of the pricing of the drug Vancomycin in 1995, as described above. The pattern is clear; the dramatically changing AWP was based upon Abbott's reporting of list prices to the Publishers.

Abbott's price reductions after Congressional inquiries and media scrutiny, (US-A-SF ¶

58), reveal that Abbott controlled the AWPs at issue. Abbott's conduct in maintaining, increasing and then lowering the inflated published prices for its drugs in 2001 reflects that the pricing information up to May 2001 was false.

2. Abbott's Actual Sales Prices Were a Fraction of the Reported List Prices, Creating Mega-Spreads.

During the course of the litigation, the United States received actual sales transaction data from Abbott for the Subject Drugs. Appendices 1-44 to the Ormond Declaration show the average sales price for each of NDCs of the Subject Drugs at issue in this action. (US-A-SF ¶¶ 19-21) Appendix 45 is a chart showing the differential or spread between the AWP and the average sales price (ASP) for each drug in this case. (US-A-SF ¶ 22) As shown by the data reflected in the chart, the spreads on all the drugs at issue ranged from 113 percent to 1652 percent. (US-A-SF ¶ 22) Every spread at issue in this case was a mega-spread, as defined in previous rulings of the Court. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 20, 31, 40 (D. Mass. 2007). As discussed further below, Abbott's creation and maintenance of mega-spreads on these drugs rendered false the payment claims for these drugs. Appendices 1-44 to the Ormond Declaration set forth the specific reported and actual prices for each NDC at issue. Appendix 45 to the Ormond Declaration summarizes the actual mega-spreads.

3. Abbott's Reporting of the Pricing Information to the Publishers Constituted False Statements and Rendered the Claims False.

Attached as exhibits to the Lavine Declaration are the documents transmitting the false and fraudulent pricing information to the Publishers used by Medicaid and Medicare to set payment levels for the drugs at issue. (US-A-SF ¶¶ 22-30). Based on the plain meaning

definition of AWP adopted in these matters,[15] this Court has held that AWP and WAC prices that have no relationship to the actual prices paid by the defendants' customers are false. *In re Pharm. Indus. Average Wholesale Price Litig*., 491 F. Supp. 2d at 103, 105-08 (D. Mass. 2007); *In re Pharm. Indus. Average Wholesale Price Litig*, 520 F. Supp. 2d 267, 270 (D. Mass. 2008). Abbott has conceded that the reported prices on the Subject Drugs bore no relation to the prices generally and currently paid to the overwhelming majority of its customers. (US-A-SF ¶ e4). These transmittals are false statements about the price of Abbott's drugs. *See* U.S. Common Brief. Based on the above facts and legal analysis both in this brief and in the common brief, the government's use of these false or fraudulent prices to set payment levels made Abbott's statements to the Publishers material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B).

It is significant that this Court's prior rulings are completely consistent with government policies that sought to pay for drug ingredient costs in the Medicaid and Medicare programs at or around estimated acquisition cost.[16] *See* U.S. Common Brief at § III(B)(1). As noted in the common brief and the statement of facts for the common brief, state Medicaid programs used Abbott's AWPs to set payment levels for the cost of Abbott's drugs. *See* U.S. Common Brief at

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[15]*In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 287 (D. Mass 2006).

[16]This Court has recognized that defendants' claim that "they have *carte blanche* to publish sky-high prices unmoored from the acquisition costs of providers leads to absurd results." *See State of California ex. rel. Ven-A-Care v. Abbott*, 478 F. Supp. 2d 164, 173 (D. Mass. 2007). The Court has further noted that drug prices which "cross any reasonably drawn line between estimates which reasonably reflect prices paid by providers and estimates which are so grossly inflated when compared to actual acquisition costs . . . are by their very nature fraudulent." *Id.* at 174.

§ III(B)(2), (US-C-SF ¶¶ 25-84). Claims reimbursed off of Abbott's inflated AWPs were false and/or fraudulent, in violation of 31 U.S.C. § 3729(a)(1). *See* U.S. Common Brief at § III(A). The fraud underlying the claims is material for the same reasons the false statements are material.

B. The United States Is Entitled to Partial Summary Judgment Regarding Materiality and Causation for False Claims Involving the Medicaid Program.

The United States addresses materiality and causation together because the factual premises are intertwined. As set forth in the Common Brief, materiality is defined as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. *See* U.S. Common Brief § III(C). *See also Commonwealth of Massachusetts v. Mylan*, 608 F. Supp. 2d 127, 153 (D. Mass. 2008); *United States ex rel. Longhi v. Lithium Power Techs., Inc*., 2009 WL 1959259 at *8 (5th Cir. 2009) ("All that is required under the test for materiality, therefore, is that the false or fraudulent statements have the potential to influence the government's decisions.")[17]

The Myers and Stauffer summaries show how these reported prices were used by government agencies to pay for Abbott's drugs. *See* Henderson Declaration attached to the U.S. Common Brief (Henderson Common Decl.) (US-C-SF ¶¶ 36-84). As shown in these summaries, the manufacturer's AWP – discounted by a modest percentage – was used as a proxy for estimated acquisition cost by the vast majority of states during the claims period. (Henderson Common Decl. Ex. 24). The United States has further explained how the federal government then pays for payments to providers for drug ingredient costs. (US-C-SF ¶¶ 85-91).

Abbott HPD Alt Site employees have acknowledged their understanding of the

[17]In addition, FERA codified this materiality standard in 31 U.S.C. § 3729(b)(4), Pub. L. No. 111-21, § 4(b)(4).

"unmoored" character of Abbott's list prices or that the prices Abbott reported impacted Medicaid reimbursement. (US-A-SF ¶ 34). An HPD Alt Site reimbursement manager, Michael Heggie, testified that he knew that AWP was relevant to reimbursement and that AWP-based reimbursement was not the most economical way for Medicare to reimburse because Abbott's list price was significantly higher than the sales price. (US-A-SF ¶ 34). Mr. Heggie understood the disconnect between reimbursement rates and high list prices. He admitted that AWP-based reimbursement was a function of Abbott's reporting of list price. (US-A-SF ¶ 34). Christine Snead, a National Account Manager, similarly conceded that it was common knowledge in the marketplace that Abbott's customers used AWP for reimbursement. (US-A-SF ¶ 32)

AWPs and spreads were directly material to claims for payment submitted by Abbott's Home Infusion business. Abbott's Home Infusion contract marketing manager, David Brincks, testified that, because there were such large spreads between AWP-based third party payments for drugs received by Home Infusion partners and the actual cost of the underlying products, Abbott could recover its product costs and costs of services under the Home Infusion contracts, even taking in just a 15 percent recovery of a customer's reimbursement. (US-A-SF ¶¶ 146-147).

As to whether Abbott caused false claims to be presented, the test is as this Court set forth in *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255, at * 4 (D. Mass. Aug. 22, 2003). First, the court should examine whether a defendant's conduct was a "substantial factor" in causing the presentation of false claims to the Medicaid program. Second, the court needs to examine whether the submission of false Medicaid claims by providers was a foreseeable consequence of Abbott's conduct.

By reporting false prices to the compendia used by state Medicaid programs to estimate

drug ingredient costs, Abbott caused providers to submit false or fraudulent claims for Medicaid reimbursement on Abbott's drugs. The Medicaid payment data confirms that the Medicaid program (1) paid for the Abbott NDCs at issue and (2) at levels pegged to the inflated AWPs. (US-C-SF ¶¶ 36-85, 116-120, 150, 153). This Court has already determined that the reporting of prices not reflective of actual transaction prices is sufficient to cause the presentment of inflated provider claims where reimbursement is calculated based on those prices. *See State of California ex. rel. Ven-A-Care v. Abbott*, 478 F. Supp. at 175 (D. Mass. 2007). Since the United States has demonstrated that (1) Abbott reported the false AWPs to the compendia for the Subject Drugs; (2) claims for payment for Abbott's Subject Drugs were presented to state Medicaid programs and, ultimately, the United States; and (3) the majority of states used Abbott's false AWPs to estimate acquisition cost for its drugs, the United States has established that Abbott caused false claims to be presented.

To the extent Abbott argues that payment levels may have been affected by a state MAC or another price other than its reported AWPs or WAC, that is a damages issue to be resolved at trial. It is not an issue pertinent to determining Abbott's liability. *Mylan*, 608 F. Supp. 2d at147 (liability issue is not about payment of claims); *see also United States ex rel. Fago v. M & T Mortg. Corp.*, 518 F. Supp. 2d 108 (D.D.C. 2007) (distinguishing between FCA causation as a matter of liability and causation as an FCA damages issue).

C. The United States Is Entitled to Partial Summary Judgment That Abbott's Conduct Related to the Submission of False Claims was Knowing or, at a Minimum, in Reckless Disregard.

1. The evidence demonstrates Abbott acted knowingly.

For purposes of the FCA, "knowledge" that the statement or document was false or

fraudulent means that the defendant: (1) had actual knowledge that the claim was false; (2) acted in deliberate ignorance of the truth or falsity of the claim; or (3) acted in reckless disregard of the truth or falsity of the claim. No specific intent to defraud is required. 31 U.S.C. § 3729(b); *United States ex rel Loughren v. Unumprovident Corp.*, 2008 WL 4280133 at *3 (D. Mass. Sept. 15, 2008); *Longhi*, 2009 WL 1959259 at *7; *United States ex rel. Quirk v. Madonna Towers, Inc.*, 278 F.3d 765, 767 (8th Cir. 2002). Based on undisputed evidence, it is apparent that Abbott had the requisite knowledge about the falsity of the claims at issue.

Abbott was party to a Rebate Agreement with the United States, and from 1991 through 2001, was enrolled as a provider in the Medicare and Medicaid program, as well. (US-A-SF ¶¶ 4-12) As this Court noted:

> having entered into the rebate agreements, [a defendant is] required, as a matter of law, to familiarize [itself] with the legal requirements, standards and procedures of the Medicaid program., *Heckler v. Community Health Servs.*, 467 U.S. 51, 63-65 (1984). These include the procedures and legal requirements applicable to reimbursements. *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir.2001). [A defendant is] required to know that the Commonwealth's EAC was 'the agency's best estimate of the price generally and currently paid by providers.'

Mylan, 608 F. Supp. 2d at 154. Abbott had an obligation to familiarize itself with the legal requirements, standards and procedures of the Medicaid program. Ignorance of the law is no defense to its false price reporting and the resulting damage to the government programs; indeed, it constitutes affirmative evidence of Abbott's deliberate ignorance of its obligations as a direct participant in, and as a manufacturer whose products are reimbursed under, the Medicare and Medicaid programs. Deliberate ignorance of the truth or falsity of claims meets the FCA's "knowledge" requirement. *Id.* at 154-155.

a. Abbott's Knowledge By Virtue of Its Own Participation As a Provider and a Partner of Providers

The undisputed evidence shows that Abbott knew, or was deliberately ignorant or reckless about, the falsity of its reporting to the Publishers and the effect of its conduct on the Medicaid program. Home Infusion's business model involved, in part, collecting or sharing in the reimbursed spreads on the Subject Drugs in exchange for the provision of Abbott products, and for the provision of services, at no separate cost. (US-A-SF ¶¶ 134-141**)** Abbott concedes that Home Infusion employees within HPD were familiar with how Medicare and Medicaid reimbursed; those reimbursement employees directly submitted claims to Medicare and Medicaid on behalf of Abbott's own pharmacies and under service arrangements with its partners. (US-A-SF ¶ 132)

By virtue of the operation of this business, Abbott had actual knowledge of the effect of its price reporting on Medicare and Medicaid. (US-A-SF ¶¶ 134-141) . Indeed, its business model depended upon high spreads from third-party payors, including Medicare and Medicaid, sufficient to cover Abbott's costs and those of its Home Infusion partners, while providing for profit. (US-A-SF ¶¶ 146-147)

b. Abbott Knew Or Was Reckless or Deliberately Ignorant About the Effect of Its False Pricing Conduct on Claims.

It is also undisputed that the list prices set and reported by the HPD HBS managers (1) were prices at which Abbott sold less than one percent (or less than .20 percent on average) of its products to HPD Alt Site customers; (2) were increased every year despite decreasing or flat average transaction prices; and (3) were astronomically higher than prices generally and currently paid for Abbott's Subject Drugs in the marketplace. (US-A-SF ¶ 62) Unlike in the *Mylan* case,

there is no sworn testimony creating an issue of fact that Abbott HPD HBS believed the prices it reported to be invoice prices. *Mylan*, 608 F. Supp. 2d at 154. Quite to the contrary, Abbott testified that it knew that these were the highest prices paid by any customer,[18] and that they were 70 percent to 90 percent higher than contract prices. (US-A-SF ¶ 57).

Both by virtue of the events in a one-month period in 1995, in which Abbott dramatically altered its pricing of Vancomycin (US-A-SF ¶¶ 71-81), and its 2001 decision to report prices reflective of the amounts generally and currently paid by providers, Abbott demonstrated that it could raise and lower its list price and knew the actual marketplace prices that customers paid for Abbott drugs. Abbott admitted it could have altered its prices at will, (US-A-SF ¶¶ 43, 49) and key Abbott employees confirmed their knowledge of how Abbott's list price affected AWP and government payment levels for Abbott's drugs. (US-A-SF ¶¶ 32-38)

The importance of AWP to Abbott's HPD Alt Site market is reflected as early as June 1991 when its vice president Donald Robertson conceded in a memo to the then-HPD president, among others, that if the government abandoned AWP as a good indicator of product acquisition cost, it would have significant implications for HPD's Alt Site business. (US-A-SF ¶ 55) In 1996, a member of Abbott's Medicare Working Group, an organization formed to monitor Medicare issues, circulated internally a memorandum highlighting that "the use of AWP as a payment measure results in excessive reimbursement that is far out-of-line with the estimated acquisition costs of the drugs" among other AWP concerns. (US-A-SF ¶¶ 119-120) This same Abbott employee, Michael Tootell, advised the Abbott in-house legal department of his concerns

[18]Abbott testified that it reported its highest prices to the Publishers and that the only prices it would make public were its highest prices. (US-A-SF ¶ 84)

about legal exposure and the negative consequences associated with AWP spreads. (US-A-SF ¶¶ 121, 127)

Abbott had a Medicare Working Group, which had an HPD representative. (US-A-SF ¶¶ 119-120) Abbott's Medicare Working Group kept abreast of reimbursement issues and used its status to participate as an industry leader on certain initiatives, including legislative initiatives. It also monitored legislation for changes in reimbursement.

Finally, during the claims period through April 2001, Abbott's joint venture with Takeda Pharmaceutical Company, TAP Pharmaceuticals, was the subject of a criminal and civil probe that resulted in a plea agreement and civil settlement with the United States and numerous states totaling nearly $850 million. Part of the civil settlement resolved allegations that TAP manipulated prices and marketed the spread. (US-A-SF ¶ 131) During the period relevant to this case, Abbott was aware of TAP's legal exposure, in part because, as a joint venturer it directly entered into a related side agreement with the United States confirming Abbott's agreement with the resolution of the TAP matter. (US-A-SF ¶¶ 130-131) Abbott's in-house lawyers, who had exclusive domain within Abbott over Medicare and Medicaid compliance, worked with TAP Pharmaceuticals on its AWP issues and problems. (US-A-SF ¶ 130**)**

2. At a minimum, Abbott Acted with Reckless Disregard as to the Truth or Falsity of Its Pricing and the Impact of its Pricing on Government Reimbursement.

Given Abbott's knowledge of its mega-spreads on certain HPD drugs, there is no genuine issue of disputed fact that at a minimum Abbott acted with reckless disregard of the truth or falsity of its prices. While the United States believes that there is ample evidence that Abbott acted with actual knowledge, even viewing Abbott's own testimony in the light most favorable to

it, there is no dispute that Abbott employees acted with reckless disregard of the truth or falsity of their prices when setting and reporting list price to Publishers.

The undisputed facts are that Abbott's price reporting, during the relevant years for the drugs at issue, evinces at least a reckless disregard for the Medicare and Medicaid reimbursement requirements. According to Abbott's testimony, no one within the HPD division was monitoring differences between list prices and contract (actual) prices for nearly ten years from 1991 until 2000, yet all the while reporting list prices to the Publishers. (US-A-SF ¶ 59) Referring to its spreads of up to 1,685 percent as inadvertent disparities, Abbott points the finger at HPD HBS managers who were responsible for price setting and reporting to the exclusion of HPD Alt Site employees during the time period from 1991 to at least 1999. (US-A-SF ¶¶ 39, 45, 50, 52)

Abbott testified that the HPD HBS pricing managers were unaware of the impact of their conduct on Medicare and Medicaid reimbursement. (US-A-SF ¶ 46) However, Abbott's employees performed their duties not in a vacuum, but in the full purview of Abbott as a corporate actor. Abbott HPD's conduct in pricing its drugs was not in line with Abbott's PPD pricing conduct. (US-A-SF ¶ 47). In the *Longhi* case, the defendants similarly defended their submission of false claims as inadvertence; the Fifth Circuit upheld the district court's summary judgment determination that the defendant acted, at a minimum, with reckless disregard in view of the defendant's distortion of its participation qualifications in the federal grant program which paid money to defendant as a grant recipient. *Longhi*, 2009 WL 1959259 at *10 (5th Cir. 2009); *see also United States v. Krizek*, 111 F.3d 934, 941-942 (DC Cir. 1997) (equating the FCA reckless disregard standard to aggravated gross-negligence, and finding reckless disregard when the wife completed claims for payment with little or no factual basis, and the physician "utterly

failed" to review the information before his submission to Medicare and Medicaid.)

For these reasons, Abbott's undisputed conduct amounts to at least reckless disregard, and summary judgment is appropriate as to the FCA scienter element for that reason alone.

D. Abbott Cannot Assert A Government Knowledge Defense.

As set forth in the U.S. Common Brief, this Court should rule that government knowledge, to the extent it is relevant in this case, is limited to its effect on a particular defendant's scienter. *See* U.S. Common Brief § III(C). Abbott asserts various defenses tacitly premised on government knowledge.[19] This Court should enter summary judgment in favor of the government on the applicability of a government knowledge-based defense to the issue of scienter, falsity or any related affirmative defenses because there is no genuine issue of material fact; Abbott cannot meet the elements of any government knowledge-based defenses.

1. Abbott cannot fulfill the prerequisites for a government knowledge-based defense to FCA falsity or scienter.

In the common brief, the United States argues that government knowledge in an FCA case is relevant only to scienter. As further set forth therein, to succeed on a government knowledge-based scienter argument, Abbott must meet three criteria: a) that it fully informed the appropriate government officials of the actual facts of the precise nature of the deviance between the Abbott's reported prices for the Subject Drugs and the actual prices generally and currently paid by providers for those products; b) that the government affirmatively approved of the

[19] *See* Thirty-Eighth Affirmative Defense ("Plaintiffs and/or its agents knew and were aware that AWP did not represent an actual average of wholesale prices or the actual acquisition cost of drugs. Legal and equitable principles preclude this action for damages and injunctive relief, and the Due Process Clause of the U.S. Constitution preclude Plaintiffs from bringing claims and seeking damages as alleged in the Complaint."). *See also* Nineteenth, Twenty-Fourth, Twenty-Fifth (Part c), and Thirty-Fifth defenses.

alleged wrongful price reporting conduct; and c) that Abbott's list price setting and reporting conduct in fact was premised on an understanding that the government had approved of the conduct at issue. *See* U.S. Common Brief § IV(C). The evidence shows Abbott cannot meet any of these elements.

a. Abbott Never Fully Informed Government Officials of the Actual Facts.

To succeed on its government knowledge-based scienter argument, Abbott must show that the "government [possessed] knowledge of the *actual true facts* of the claim, not simply knowledge that the claim is generally false." *Mylan*, 608 F. Supp. 2d at 148 (emphasis added). Abbott admitted that it never fully informed the appropriate government officials of the *actual* facts or particulars of the precise nature of the deviance between its reported prices and its contract or marketplace prices. (US-A-SF ¶¶ 105-106, 108, 112). Abbott testified that the government should have inferred the actual facts through Abbott's submission of AMP, and that 340B pricing provided the government with a picture of its transactional prices. (US-A-SF ¶ 115). This Court already has rejected an AMP theory as a basis for a government knowledge defense asserted against Massachusetts. *Mylan*, 608 F. Supp. 2d at 152. For the same reasons, Abbott's parallel argument regarding 340B pricing should be rejected as well. Even assuming, *arguendo*, that AMP and 340B pricing could constitute disclosure in support of a government knowledge defense, the evidence produced by Abbott in this case makes clear that until 2001, Abbott miscalculated its AMPs and 340b pricing.[20] (US-A-SF ¶¶ 116-117).

[20]According to Shirish Patel, the Abbott employee responsible for implementing the new system for AMP and 340b calculations, the prior system used by Abbott failed to pick up certain necessary information important to the AMP calculation. Abbott tried to correct the problem in 2000 through 2001. (US-A-SF ¶ 118) Further, as early as 1995, Abbott recognized a problem

b. The Government Never Approved of Abbott's Wrongful Price Reporting.

Abbott did not seek or receive approval for its list price setting or price reporting conduct from the United States or any state, and cannot rely upon a government knowledge defense as a result. There were no explicit directions from the government that Abbott relied upon. *See United States ex rel. Durcholz v. FKW, Inc.*, 189 F.3d 542, 545 (7th Cir. 1999); *United States ex rel. Ven-A-Care v. Abbott Laboratories*, 254 F.R.D. 35, 42-43 (D. Mass. 2008).

c. Abbott Never Acted Upon Any Government Approval In Setting and Reporting Its List Prices.

Finally, Abbott testified that its price reporting was in no way dependent on government approval. (US-A-SF ¶¶ 105-106) The testimony of Rule 30(b)(6) corporate designees showed that Abbott: a) never sought any guidance from the United States concerning its list price reporting conduct; b) never sought approval from the government for its reporting of list prices for the Subject Drugs; c) never informed the government, or any state other than Texas, of its prices currently and generally paid or charged in the marketplace for its Subject Drugs; and, d) never relied upon *any* information pertaining to Medicare or Medicaid to inform its list price setting or reporting conduct. (US-A-SF ¶ 123)

Abbott argues that it was government policy to pay inflated reimbursement. Abbott brief at 1-4, 22-25 (Dkt. No. 6186). The United States disputes this argument, but assuming *arguendo*, it was true, Abbott admitted that Medicare or Medicaid reimbursement, and/or cross-

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dating back to the inception of the OBRA 90 rebate requirements, and sought a credit on rebates it had mistakenly paid. HPD Abbott used essentially undiscounted AWP in calculating its AMPs, causing Abbott HPD, in some instances, to pay more in rebates than it was charging for the product. (US-A-SF ¶¶ 116-117)

subsidization of Medicare or Medicaid reimbursed dispensing fees and provider costs, never influenced or impacted Abbott's list pricing decisions. (US-A-SF ¶ 40) Therefore, even the alleged government policy did not inform Abbott's conduct. Accordingly, there is no genuine issue of disputed fact, and for this reason, the United States is entitled to summary judgment on Abbott's purported defense of government knowledge.

E. The United States is entitled to partial summary judgment on certain of Abbott's affirmative defenses.

Several of Abbott's affirmative defenses are variations of a "government knowledge" defense that are legally unsupportable. These arguments are addressed in the U.S. Common Brief § IV(C). The United States respectfully requests that the Court grant summary judgment on these affirmative defenses: release, laches, estoppel and waiver, a failure to mitigate damages, government knowledge, and contributory or comparative fault.

F. Opposition Arguments Unique to Abbott's Summary Judgment Motion

1. The Court Should Reject Abbott's Motion For Summary Judgment As To Claims Reimbursed On the Basis of an "AWP Proxy" For WAC.

Abbott argues that the Court should grant summary judgment on claims for which states used AWP as a proxy for unpublished WACs when AWP was not expressly included in the state's reimbursement formula. Abbott Brief at 19-20 (Dkt. No. 6186). Abbott relies on this Court's ruling in *Mylan*, 608 F. Supp. 2d at 134, 147-148, in which the Court ruled that there was "insufficient evidence in the record to find that the defendants understood they were being reimbursed on the basis of an EAC calculated using their AWPs. . . ." This ruling in the *Mylan* case was fact-specific and cannot be generally applied to this case.

Whether the issue is treated as one of "knowledge" under the FCA, 31 U.S.C. § 3729(b), or "causation" under § 3729(a), the same basic principle should apply. "If the actor's conduct is a substantial factor in bringing about harm to another, the fact that the actor neither foresaw nor should have foreseen the extent of the harm or the manner in which it occurred does not prevent him from being liable." Restatement (Second) of Torts § 435(2) (1965); *see Staelens v. Dobert*, 318 F.3d 77, 79 (1st Cir. 2003); *Nna v. American Standard, Inc.*, 2009 WL 1307955 at *10 (D. Mass. May 1, 2009).

Viewing the facts in favor of the United States as the non-moving party, there are disputes of fact about the use of AWPs in states that generally reimburse off WAC. Manufacturers signing a rebate agreement are required to "familiarize themselves with the legal requirements, standards and procedures of the Medicaid program." *Mylan*, 608 F. Supp. 2d at 155. At a minimum, Abbott was obligated to know that federal law requires states to reimburse based upon EAC. *See generally* U.S. Common Brief § III(B). Thus, manufacturers were required to know that some states used WACs rather than AWPs.[21] Further, Abbott's unique status as an actual pharmacy provider, billing and receiving payment from Medicaid programs, including those utilizing WACs, provided another avenue for Abbott to have learned that its products were covered even in circumstances where states first looked to WACs for a price. Abbott's Home Infusion pharmacy communicated directly with state Medicaid Programs and learned many

[21]Similarly, it is extremely likely that a manufacturer would become aware that a Medicaid program completely refused to cover its products. In the absence of such an event occurring and coming to the attention of a manufacturer, it is reasonable to charge a manufacturer with knowledge that its drugs were being covered. Abbott has not presented any evidence suggesting that all claims for drugs without published WACs were ever systematically denied by any Medicaid program. The only reasonable conclusion is that the drugs were being covered.

details of their policies. (US-A-SF ¶¶ 107-108) Even if we assume, *arguendo*, that information was kept away from the Abbott employees setting the prices, the evidence demonstrates that Abbott was fully capable of collecting the information through a simple inquiry to the Medicaid program.

Thus, there are sufficient facts to justify holding Abbott responsible for the damages caused to WAC states, and disputed issues of fact to prevent summary judgment against the government on this issue.

2. Abbott's Request to Curtail Damages Due To An Alleged Failure To Produce "Samples" Of Claims Should Be Denied.

Abbott has requested that the Court dramatically curtail the United States' damages based on the allegation that the government failed produce the Medicaid "claims" which underlie its damage estimates and that the government failed to produce a "sample" of the claims as purportedly required by an Order of the magistrate judge. This is simply not true. The United States has produced to Abbott both the Medicaid claims for which damages are claimed and a sample of those claims. Moreover, pertinent case law makes it clear that Abbott is not entitled to the relief it is seeking.

First, with respect to Abbott's allegation that the government has failed to produce "false claims," Abbott acknowledges that it has claims data, but complains that "all the Government produced ... was data (not claims)." Abbott brief at 19 (Dkt. No. 6186). Abbott ignores the fundamental feature of electronic claims processing: claims data is one and the same as the claim forms. Today, the only record that exists for that claim is the data submitted by the provider together with whatever information is entered regarding claims payment. Accordingly, the

electronic data comprise the "claims" in the possession of the United States, and it has been produced. *See United States ex rel. El-Amin v. George Washington Univ.*, 522 F. Supp. 2d 135, 147 (D.D.C. 2007) ("If Defendant submitted claims to Medicare electronically, then the 'claim' for purposes of the Act might, it seems, be the electronic file sent to Medicare or Defendant's Medicare carrier.")

As to the sufficiency of the type of claims information necessary to support an FCA case, a comprehensive decision by the U.S. District Court for the District of Columbia discusses the legal principles relating to the sufficiency of the evidence that may be entered at trial. *See United States ex rel. El-Amin*, 522 F. Supp. 2d 135. "[N]othing in the language of the FCA requires [plaintiff] to possess (and present to the factfinder) the actual claim form, whether it be paper or electronic, submitted to the government." *Id*. at 141-42. In fact, "Medicare billing documentation . . . may serve as circumstantial evidence that a claim was submitted to Medicare" and "is not only sufficient, but may also be more certain, satisfying, and persuasive than direct evidence." *Id.* at 143.

Notwithstanding that the United States produced *all* of its claims data in this case, it was also ordered to produce a sample as well. With respect to the format for the sample, the Magistrate Judge directed defense counsel to "sit down and work it out what it is you would like on a sample basis." Hearing Transcript of 12/4/2008 hearing before Magistrate Judge Bowler at 52. *See* Lavine Decl. Ex. 99. After the hearing, counsel for the United States asked Abbott's attorney to provide specifications for the sample. Defense counsel advised that he would refer the question to other attorneys at his firm. Thereafter, the United States did not hear from Abbott again on this issue. The government sent Abbott a sample of data on December 18, 2008. Prior

to the summary judgment motion, Abbott never challenged whether the government's sample was sufficient or compliant via a motion pursuant to Fed. R. Civ. Proc. 37(b).

In sum, the United States has produced to Abbott the underlying universe of false claims submitted, or caused to be submitted, by Abbott. A duplicative production of a lesser portion of those claims in the form of a sample also was produced to Abbott. Abbott has made no showing that the information is in any manner insufficient, or that it has been prejudiced, and thus, Abbott's summary judgment application should be denied.

3. The United States' Home Infusion Claims Are Timely and Not New.

Abbott contends that United States' allegations against Abbott concerning its Home Infusion operations are new claims that do not relate back to the relator's *qui tam* complaints. These are not new claims that seek damages or penalties that were not already part of the original complaint, but refinements to the original claims based on the revelation that Abbott was actually a provider that submitted claims for the Subject Drugs. As set forth in the Common Brief, the plain language of FERA expressly provides that the United States may *clarify or add detail* to the claims in which the government is intervening. 31 U.S.C. § 3731(c). *See* U.S. Common Brief § IV(B)(1). The FCA, as amended, clearly permits the relation back of these claims.[22] *U.S. ex rel. Bunk v. Birkart Globistics GmbH & Co.*, No. 1:02cv1168 (E.D. Va. July 20, 2009).

[22]Even without this clear statutory requirement, the case authority cited by Abbott was inapposite because the Home Infusion allegations in the Amended Complaint involve the same conduct, transactions and occurrences in relator's original complaint because they involve the submission of claims for the Subject Drugs that were at issue in relator's original complaint.

IV. CONCLUSION

For the reasons stated above, the United States requests that the Court grant it partial summary judgment on the elements of falsity, materiality and causation on its FCA Medicaid claims, and summary judgment on Abbott's defense of release, laches, estoppel and waiver, failure to mitigate damages, government knowledge and contributory or comparative fault.

Respectfully submitted,

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I hereby certify that I have this day caused an electronic copy of the above **UNITED STATES' MEMORANDUM OF LAW IN SUPPORT OF CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT AND IN OPPOSITION TO ABBOTT LABORATORIES INC.'S PARTIAL MOTION FOR SUMMARY JUDGMENT** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Mark Lavine

Dated: July 24, 2009 Mark Lavine